comprising 240 ng to 650 mg of a member selected from the group consisting of oxybutynin and its pharmaceutically acceptable salt, that releases the member at a rate of 0.05 mg per hour up to 0.850 mg per hour for about 24 hours.

32. (Amended) A pharmaceutical dosage form comprising 240 ng to 650 mg of a member selected from the group consisting of oxybutynin and its pharmaceutically acceptable salts, the dosage form being adapted to release the member at a controlled and sustained rate for about 24 hours.

33. The dosage form of claim 32 wherein the controlled and sustained rate is substantially zero order.

REMARKS

This amendment is filed in response to the Office Action dated July 5, 2001.

Claims 1, 32 and 33 are pending in the application.

Claims 1, 32 and 33 are rejected under 35 U.S.C. § 112, first paragraph, because the specification does not reasonably provide enablement for oxybutynin and its pharmaceutically acceptable salt.

Claims 1, 32 and 33 are further rejected under the judicially created doctrine of double patenting over all claims of U.S. Patent Nos. 5,674,895; 5,840,754; 5,912,268; and 6,262,115.

Claim Rejections – 35 U.S.C. § 112, first paragraph

Claims1, 32 and 33 are rejected under 35 U.S.C. §112, first paragraph, because the specification does not reasonably provide enablement for oxybutynin and its pharmaceutically acceptable salt. In particular, the Examiner asserts that the specification does not enable any person skilled in the art to make the invention commensurate in scope with these claims. The Examiner states that Applicants disclose use of 240 ng to 650 mg of oxybutynin and its pharmaceutically acceptable salt released over a 24-hour period.

Applicants amend independent Claims 1 and 32 to claim the disclosed range of oxybutynin and its pharmaceutically acceptable salts and the release period disclosed.

Accordingly, Applicants respectfully request that the Examiners rejection be withdrawn and the application proceed to issuance.

Double Patenting

Claims 1, 32 and 33 are rejected under the judicially created doctrine of obviousness-type double patenting over all claims of U.S. Patent Nos. 5,674,895; 5,840,754; 5,912,268; and 6,262,115. Applicants respectfully traverse because the instant application and the cited patents are owned by the same entity and a terminal disclaimer may be appropriate when claims are allowed.

Accordingly, Applicants will file a terminal disclaimer when claims of the instant application are allowed.

Reconsideration of the application is respectfully requested.

Accordingly, Applicants believe that the present application is in a condition for allowance. Should any further changes be deemed necessary, the Examiner is invited to contact the undersigned attorney at the telephone number provided.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned **"Version with markings to show changes made."**

The Commissioner is hereby authorized to charge any additional fees associated with this paper or during the pendency of this application, or credit any overpayment, to Deposit Account No. 01-1173.

Respectfully submitted,

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Version with markings to show changes made

In the Claims:

1. (Amended) A method for the management of incontinence in a patient, wherein the method comprises admitting orally into the patient a dosage form comprising 240 ng to 650 mg of a member selected from the group consisting of oxybutynin and its pharmaceutically acceptable salt, that [is administered] releases the member at a [release] rate of 0.05 mg per hour up to 0.850 mg per hour for about 24 hours [for the management of incontinence in the patient].

32. (Amended) A pharmaceutical dosage form comprising 240 ng to 650 mg of a member selected from the group consisting of oxybutynin and its pharmaceutically acceptable salts, the dosage form being adapted to [be administered once-a-day and] release the member at a controlled and sustained rate for about 24 hours.

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